

REMARKS

Applicants respectfully request reconsideration and allowance of this application in view of the amendments above and the following comments.

Regarding the restriction requirement, Applicants hereby affirm their election with traverse of Group I, claims 1 and 3-6, and the species of Example 4. Currently, all of the claims, with the exception of claim 5, are believed to read on the elected species.

Applicants respectfully request that the Examiner reconsider and withdraw the restriction requirement, or at least modify it. Currently, the Examiner has examined the case to the extent it reads on monomer oligopeptide VVRP, its amide or N-acetyl derivative. Thus, for example, the elected invention apparently excludes such structurally close N-acyl amides as are depicted in claim 5. Respectfully, the Examiner has not taken much upon himself, and would apparently require Applicants to file a large number of divisional applications in order to get the whole of claim 1 examined. This places too much of a burden on Applicants. Applicants' original thought was that the case was being divided evenly among monomers, dimers, trimers and tetramers. However, the Examiner now breaks up these groups further, with no indication, and no way of knowing, exactly how many divisionals would be necessary in order to get the whole of claim 1 examined.

Applicants would remind the Examiner that in order for the Examiner to

insist upon restriction, there must be a serious search burden if restriction is not required. MPEP § 803. The Examiner has not shown, for example, that the search of structurally close N-acyl amides as are depicted in claim 5 could not be made without a serious search burden. Consequently, Applicants submit that the Examiner should broaden the "elected" invention to include other structurally close monomer oligopeptides, such as those which are depicted in claim 5.

Further, with regard to method claims 2 and 7-10, the traversal is on the grounds that the subject matter of these claims should be examined together with Group I. It is customary for one method of use to be considered along with product claims. Failing that, Applicants would call the Examiner's attention to the Commissioner's Notice published in the Official Gazette on March 26, 1996, at 1184 OG 86. According to that notice:

"[A]pplicant may be called upon under 35 U.S.C. § 121 to elect claims to either the product or the process. The claims to the non-elected invention will be withdrawn from further consideration. However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim depends from and otherwise includes all the limitations of an allowed product claim."

Applicants presume that the Examiner is proceeding in accordance with this notice, and that the subject matter of Group II will be joined in the event that the subject matter of Group I is found to be allowable. If this procedure will not be followed, then Applicants would appreciate an explanation from the Examiner of why this

notice is not applicable, or why some deviation therefrom is warranted.

Regarding the Sequence Listing, Applicants submit a paper copy of the Sequence Listing and a computer readable form thereof. Regarding the paper copy of the Sequence Listing, the undersigned hereby certifies that the paper copy of the Sequence Listing does not introduce new matter. The undersigned hereby further certifies that the content of the attached computer readable form is identical to the paper Sequence Listing provided. No new matter has been added to the computer readable form.

With respect to the use of sequence identifiers in the claims, Applicants respectfully request that this requirement be held in abeyance until allowance subject matter is indicated, at which time Applicants will supply the missing material. See 37 CFR § 1.111 (b) ("[A] request may be made that objections or requirements as to form not necessary to further consideration of the claims be held in abeyance until allowable subject matter is indicated.")

Regarding the objection to claim 1, Applicants point out that the objectionable terminology has been deleted.

Claims 1, 3, 4 and 6 were rejected under 35 USC § 112, second paragraph, as being indefinite. In response, Applicants have replaced the language "distinguished by" in claim 1 by the term "comprise" in accordance with the Examiner's suggestion. Also, the narrower ranges of claims 1 and 6 have been deleted, and the narrower

ranges of claim 6 have been made the subject of new claims 11 and 12.

Claims 1 and 3 were rejected under 35 USC § 103(a) as being obvious over Kohmura et al. ("Kohmura"), Agric. Biol. Chem., 54: 835-836 (1990). The Examiner finds that persons skilled in the art would have been motivated, given Kohmura, to prepare a pharmaceutical composition comprising peptides of Kohmura as an active ingredient therein because Kohmura teaches that these peptides inhibit ACE activity and therefore may be useful in treatment of ACE-mediated processes, such as regulation of blood pressure. In response, Applicants submit that the Examiner has not made out a prima facie case of obviousness.

Specifically, Applicants would call the attention of the Examiner to Kohmura in the last sentence in the last full paragraph in the left-hand column on page 836. There, Kohmura expressly teaches "[f]urther work, however, will be needed to conclude whether these active peptides have a physiological meaning in blood pressure regulation." Thus, whereas the Examiner concludes that persons skilled in the art would have been motivated to make pharmaceutical compositions containing Kohmura's peptides as active ingredients, and to use them in the treatment of ACE-mediated processes, such as regulation of blood pressure, Kohmura himself evidences a lack of such motivation by teaching no then known correlation between the activity demonstrated and blood pressure regulation.

Applicants would remind the Examiner that prima facie obviousness requires a reasonable expectation of successfully making and using the claimed invention for

some practical purpose. Here, where the prior art expressly indicates that there is, in fact, no reasonable expectation of successfully using the claimed invention for any practical purpose, then a prima facie case of obviousness cannot have been made out. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

Claims 1 and 3 were rejected under 35 USC § 103(a) as being obvious over Kohmura in view of Atlas of Protein Sequence and Structure (Vol. 5, 1972). In response, Applicants point again to the defects of Kohmura which are noted above. The "Atlas" was cited only to show certain conservative substitutions for Val, and, therefore, does not cure any of the defects of Kohmura. Accordingly, the cited combination of references cannot render obvious the rejected claims, and Applicants respectfully request that the Examiner reconsider and withdraw this rejection as well.

Claims 1, 3 and 4 were rejected under 35 USC § 103(a) as being obvious over Kohmura in view of Bundgaard (Design of Prodrugs, Chapter 1, 1985) and Sumner-Smith, U.S. Patent No. 5,646,120. In response, Applicants point again to the defects of Kohmura which are noted above. Bundgaard is cited to show administration of peptides in the form of prodrugs, and Sumner-Smith is cited to show the use of the acetyl group to protect the amino terminal group, and the use of amido to protect carboxyl terminal group. Consequently, neither Bundgaard nor Sumner-Smith cures any of the defects of Kohmura. Accordingly, the cited combination of references cannot render obvious the rejected claims, and Applicants respectfully

request that the Examiner reconsider and withdraw this rejection as well.

Claims 1 and 3 were rejected under 35 USC § 102(e) as being anticipated by Steffens et al. ("Steffens"), U.S. Patent No. 5,681,721. In response, Applicants point out that the instant claims are drawn to "[c]osmetic or dermatological topical preparations." The compositions of Steffens appear to be injectable formulations. See Steffens at column 6, lines 1-2. Accordingly, there is no anticipation. Therefore, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

Claims 1 and 3 were rejected under 35 USC § 103(a) as being obvious over Steffens in view of Atlas of Protein Sequence and Structure (Vol. 5, 1972). In response, Applicants point again to the defects of Steffens which are noted above. The "Atlas" was cited only to show certain conservative substitutions for Val, and, therefore, does not cure any of the defects of Steffens. Accordingly, the cited combination of references cannot render obvious the rejected claims, and Applicants respectfully request that the Examiner reconsider and withdraw this rejection as well.

Claims 1 and 6 were rejected under 35 USC § 103(a) as being obvious over Kohmura or Steffens. In response, Applicants point again to the defects of Kohmura and Steffens which are noted above. To the extent that there are concentration differences between the instant claims and the formulations of Kohmura or Steffens, then these would be in addition to the defects noted above,



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which are not bridged by any cited reference. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this rejection as well.

Applicants believe the foregoing constitutes a full and complete response to all outstanding objections and rejections.

Early and favorable action is earnestly solicited.

Respectfully submitted,

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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231 on the date indicated below:

Date November 24, 1999

By   
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